

**Before the United States
Environmental Protection Agency**

**Procedures for Chemical Risk Evaluation
Under the Amended Toxic Substances Control Act
(Docket EPA-HQ-OPPT-2016-0654)**

Comments of the Chemical Users Coalition

The U.S. Environmental Protection Agency recently issued for comment a proposed rule under Section 6 of the Toxic Substances Control Act (“TSCA”), at 82 Fed. Reg. 7562 (January 19, 2017), that would establish a process for conducting risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under this section of TSCA. (Hereinafter, the “Risk Evaluation Rule”.) This proposed rule raises important precedential issues for the TSCA program, as modified by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (“LCSA”). The Chemical Users Coalition (“CUC”) appreciates the opportunity to provide comments concerning those issues.

CUC is an association of companies from diverse industries that are interested in chemical management policy from the perspective of those who use, rather than manufacture, chemical substances.¹ CUC believes in the importance of aligning protection of health and the environment with the pursuit of technological innovation, two goals that can and must be made compatible if our society is to achieve sustainable economic development. Aligning these goals is particularly important in the area of chemical management policy, which necessarily addresses how core technologies and products should be adapted to address emerging information about health and environmental risk.

CUC supported passage of the Frank R. Lautenberg Chemical Safety Act (“LCSA”) and has a strong, continuing interest in implementation of the new law to assure that it results in an effective and efficient TSCA program. In commenting on the proposed Risk Evaluation Rule, CUC urges EPA to maintain its flexibility to focus risk evaluations on the most significant exposures and to obtain useful information throughout the course of the evaluation process. Specifically, we will be offering comments on certain preamble statements regarding the “scoping” step in the risk assessment process and the novel “issue preclusion” in §702.39(c)(6)(iii).

¹ The members of CUC are Intel Corporation, Procter & Gamble Company, American Honda Motor Corporation, Lockheed Martin Corporation, HP Incorporated, IBM Company, The Boeing Company, General Electric Company, and Airbus S.A.S.

1. EPA Should Not Commit Itself to Evaluating Every Condition of Use for Every Use in a Risk Evaluation

In the preamble to the proposed Risk Evaluation Rule,² EPA provides an explanation for why it has decided to have each risk assessment “encompass all manufacture, processing, distribution in commerce, use and disposal activities that constitute the conditions of use.” This decision has significant strategic and practical implications for the TSCA program. We view this decision as unnecessary and ultimately counterproductive in serving the broader purpose of TSCA to improve chemical management in this country.

a. Assessing every condition of use is not required by law

Section 6(b)(4)(D) specifies that EPA shall publish early in the risk evaluation process the “scope” of the risk evaluation “to be conducted”. EPA’s decision under this provision determines the limit of TSCA’s preemption of state law, under Section 18(a)(1)(B). Specifically, state restrictions of a chemical substance that address conditions of use not covered by EPA’s scoping decision for the substance’s TSCA risk evaluation would not be preempted by the Agency’s decision under Section 6.

Section 6 does not explicitly require EPA to regulate all of the conditions of use that the Agency identifies at the outset of its risk evaluation process. In fact, the statute, by virtue of its structure, anticipates that EPA would not address all conditions of use in at least some cases. If Congress intended for EPA to address all conditions of use in every evaluation, a scoping decision on the conditions of use, along with the deadlines for publication of the decision and the cross-referenced limit on the scope of state law preemption would not be necessary. Instead, if Congress had intended to adopt the EPA-proposed approach, the statute would simply have said that risk evaluations must evaluate every identified condition of use and there would not be any conditions of use remaining to be exempted from preemption under the provision of Section 18 noted above.

In its preamble discussion of this issue, the Agency states, “EPA acknowledges that different readings of the law may be possible”, including a reading that would allow a narrowing of the conditions of use to be considered in the risk evaluation as a means of focusing on the most significant risks.³ EPA rejects this alternative reading of the statute,

² 82 Fed. Reg. 7562 (January 19, 2017) (“FR Notice”), at 7565-66.

³ FR Notice, at 7565.

however, based on a conclusion that “the statutory text and purpose are best effectuated through a more encompassing reading” of Section 6(b)(4)(D).⁴

The only textual analysis EPA offers to explain this interpretation relies on the provision in Section 6(b)(4)(A) stating that EPA must conduct a risk evaluation to determine whether a chemical substance presents an unreasonable risk “under the conditions of use.” EPA focuses on the term “the” in that phrase, concluding that the term “is best interpreted as calling for evaluation that considers all conditions of use.”⁵ The remainder of the preamble discussion of EPA’s interpretation relies on a set of policy and administrative arguments that are not grounded on the statute per se.

There is no principle of statutory interpretation that equates a word like “the” with the word “all” as a general matter.⁶ Particularly where EPA has acknowledged, as noted above, that “different readings of the statute are possible”, it is fairly clear that EPA’s decision that all conditions of use must be addressed in every risk evaluation is essentially a policy decision that is not dictated by the specific terms of the statute. EPA has made a policy decision on this topic that can be, and should be, revisited.

b. There are compelling reasons for EPA to maintain its flexibility during the scoping process to decide that conditions of use presenting no significant risk should not be pursued in a Section 6 risk evaluation

The wide range of chemical applications that fall within the expansive range of TSCA include uses involving very small volumes of a specific substance, uses that are conducted in highly controlled, closed systems where exposure is essentially nonexistent, and uses for which any residuals from an industrial process are completely destroyed. There also are additional situations where a combination of these factors, or potentially other factors, provide assurance that the potential for exposure or environmental release from the substance’s conditions of use do not present an unreasonable risk, under any plausible reading of the unreasonable risk standard.

EPA should decide, and explain publicly, how it will address these situations during the risk evaluation process. CUC sees the scoping decision as a point in the process where EPA clearly can, as a matter of law, make a decision to drop specific uses or conditions of use that do not present significant risk

⁴ Id.

⁵ Id.

⁶ It is worth noting that EPA’s statutory analysis does not address the relevance of the statutory cross-reference to Section 18(a)(1)(B), which anticipates that EPA scoping decisions would include decisions that declined to cover some conditions of use, as explained in these comments.

from further evaluation. There are several reasons why EPA should take advantage of this option.

First, risk evaluations focused on minimal risk scenarios create obligations for information collection and analysis that waste time and resources for all parties involved. As a general matter, companies would not logically collect information about chemical exposures from a closed-system process, and EPA cannot “assess exposures” in that context because exposures do not exist. Similarly, when established waste management processes (e.g., industrial incineration at known temperatures) are known to destroy certain chemicals, EPA can quickly conclude that such disposal options do not necessitate further consideration in a risk evaluation. To include these types of situations in a risk evaluation would not contribute in a meaningful way to the Agency’s, or the public’s, understanding of the actual risk associated with the substance. These are examples of “conditions of use” that can be readily addressed, and eliminated, at the scoping stage. A policy that precludes such an option reduces the effectiveness and efficiency of the TSCA program.

Second, retaining known non-risk scenarios in a TSCA Section 6 risk evaluation creates a serious risk communication problem for EPA and the business community. Public stakeholders will reasonably assume that EPA would not initiate a risk evaluation on conditions of use for which it did not have a concern. Specifically, they would not assume that EPA had adopted a tortured reading of the word “the” in a statute to conclude that it had to assess every condition of use, no matter what potential risks they presented. Thus, EPA’s reluctance to eliminate any non-risk condition of use at the scoping stage simply invites public misunderstanding about chemical risks in American society. As a simple but likely example, they might assume that a chemical used as a process aid in a manufacturing process, which is then destroyed in that process, would be present in the end-use consumer product that results from that manufacturing. There is no LCSEA mandate requiring EPA to create consumer concerns of this kind, as well as the related communications challenge for the Agency and the business community.

Third, it is inevitable that expanding the scope of risk evaluations, beyond what is necessary to evaluate potential unreasonable risks, creates a resource and analytical burden that will undercut the broader purposes of the statute. Whether the burden associated with EPA’s approach leads to longer timeframes for individual risk evaluations (and missing deadlines) or simply to a reduction in the number of risk evaluations initiated, the net result is the same – EPA will not be addressing as many actual chemical risks to the public and to the environment as it might have been able to accomplish with a more strategic, risk-focused approach.

Fourth, EPA’s position that a risk evaluation must include all conditions of use is having a broader effect on the TSCA program, undermining the public’s

ability to influence the agenda for the Section 6 existing chemical program. On February 27, 2017, EPA issued a Federal Register notice explaining its denial of a petition filed under Section 21 of TSCA by a group of citizen and health groups seeking action under Section 6 to prohibit “the purposeful addition of fluoridation chemicals to U.S. water supplies.”⁷ While this petition was denied, in part, on grounds related to the adequacy of the scientific record submitted by the petitioners, EPA explained that an “independent ground” for denial of the petition was that it did not “comprehensively” address all conditions of use of the fluoridation chemicals, but rather “requests to take action on a single condition of use (water fluoridation).”⁸

EPA’s explanation of this position is grounded on its legal position that Section 21 “implicitly incorporates the statutory standards that apply to the requested action,” which is a Section 6 prohibition in this petition.⁹ EPA then states “EPA has interpreted the amended TSCA as requiring that forthcoming risk evaluations encompass all manufacture, processing, distribution in commerce, use and disposal activities that the Administrator determines are intended, known or foreseen.”¹⁰ Based on this logic, EPA concludes that the fluoridation chemicals petition was inadequate because it did not address “the full set of conditions of use for a chemical substance” and thus did not describe “an adequate rule under TSCA section 6(a)” that would reduce unreasonable risks “under all conditions of use.”¹¹ Thus, EPA’s position that all risk evaluations must address every condition of use is already having an adverse, and unnecessary, effect on the ability of the public to utilize Section 21, a long-standing TSCA mechanism used by many stakeholders to bring issues of concern before the Agency.¹²

We would note that in the preamble to the proposed Risk Evaluation Rule EPA has postulated some unpersuasive policy and administrative arguments to support its position that a risk evaluation must address all conditions of

⁷ 82 Fed. Reg. 11878 (February 27, 2017). EPA formally denied the petition by letter sent to the petitioners on February 17, 2017.

⁸ Id., at 11881.

⁹ Id., at 11879.

¹⁰ Id., at 11880.

¹¹ Id.

¹² CUC does not take a position on the merits of the fluoridation chemicals petition, nor its request for action under TSCA. We mention this situation only to underscore that EPA’s decision to address all conditions of use in every risk evaluation has policy effects beyond the risk evaluation itself.

use. First, EPA argues that if it had the power to narrow the uses of concern, the Agency “could determine that a chemical substance with 10 known uses does not present an unreasonable risk of injury based on an evaluation of a single one of those uses.”¹³ EPA seems to imply in this statement that it would be an abuse of power by the Agency to do this. In the case where a single use dominates the exposure profile of a chemical substance and accounted for the principal risk of concern, such an action could be the responsible strategy. In contrast, if EPA focused on one of ten uses and ignored other important conditions of use that contributed significantly to the overall risk of a substance, the Agency would be ignoring its responsibilities under Section 6(b)(4)(A) “to determine whether a chemical substance presents an unreasonable risk”, a step that CUC does not presume EPA would take and is astonished that EPA is suggesting it might take.

Second, EPA suggests that focusing on the conditions of use that contribute to the principal risk of a substance would somehow lead inevitably to a situation where the Agency would “continually need to re-evaluate chemical substances based on different subset of uses.”¹⁴ We do not understand the logic of this supposition. If EPA examines the potential conditions of use and makes reasonable determinations about the conditions use that do and do not contribute significantly to risk, based on evidence present during the scoping stage, it cannot be assumed that “continual re-evaluation” of that determination would be necessary or inevitable.

Third, EPA expresses concern that “if the law is read as allowing EPA to select particular conditions of use, it provides no criteria for EPA to apply in making such a selection.”¹⁵ In fact, the statute provides multiple sources for crafting the criteria that EPA could use for this decision, including

- The criteria that guide Prioritization as defined through rulemaking under Section 6(b)(1)(A);¹⁶
- The criteria EPA used to assemble its Workplan Chemical List in 2014;

¹³ FR Notice, at 7566.

¹⁴ Id.

¹⁵ Id.

¹⁶ See EPA’s recently proposed rule on Prioritization. 82 Fed. Reg. 4825 (January 17, 2017). The proposed rule seeks comment on a variety of criteria that may be used to identify high-priority chemical substances. Once that rule is finalized, EPA could use some of those criteria in making determinations about conditions of use that warrant attention in a risk evaluation.

- The statutory definitions of key terms modifying the unreasonable risk standard under Section 6, including the definitions for “conditions of use” and “potentially exposed or susceptible subpopulation”;
- The requirements for a risk evaluation under Section 6(b)(4)(F); and
- The scientific standards set forth in Section 26(h), which apply to decisions “based on science” under Section 6.

c. If EPA maintains its position that insignificant uses cannot be excluded from a risk evaluation at the scoping stage, EPA should consider use of its flexibility to issue risk evaluation in phases as a mechanism to evaluate and end further consideration of insignificant uses

As explained above, CUC strongly urges EPA to maintain its flexibility to remove insignificant potential risks from its risk evaluations at the scoping stage of an evaluation. If, however, the Agency decides not to allow itself such flexibility, it should consider using other mechanisms available in the risk evaluation process to remove, with an explanation, insignificant risks from further consideration.

Specifically, EPA has included a provision in the proposed rule, at §702.39(a)(6), stating “EPA may conduct a risk evaluation on a chemical substance in phases”. As drafted, this provision appears aimed at expediting an evaluation for conditions of use that would present relatively high potential risks. This concept, however, could also be used to expedite and close the risk evaluation on conditions of use that do not contribute significantly to the overall risk of the chemical substance under review. As noted above, there will inevitably be many conditions of use that fall into this category, particularly in industrial settings. Removing them from further analysis during the early stages of the risk evaluation process would help focus the Agency’s risk evaluation work, and help the public understand what the real concerns are about chemical substances under review.

As noted above, CUC recommends that EPA allow for removal of conditions of use presenting insignificant risks at the scoping stage. We also recommend modifying the language of §702.39(a)(6) to allow for expedited decisions on the removal of such conditions of use as a “phase” in the overall risk evaluation process.

2. EPA Should Maintain Flexibility to Correct Errors in Its Assumptions about Conditions of Use

In the preamble to the proposed Risk Evaluation Rule, EPA states, “in this proposed rule EPA proposes to ‘lock down’ the conditions of use included in a risk evaluation at the time of scoping, by providing opportunity for comment on the scoping document and specifying that any objections to the draft scope document are waived if not raised during the process.”¹⁷ We will address the specifics of this waiver provision in the next section of these comments, but it is important to address here a broader and more fundamental point about the Section 6 risk evaluation process.

EPA’s Section 6 program will lose all credibility if its risk evaluations are not accurate. Certainly a risk evaluation based on faulty assumptions about how a chemical substance under review is used will not be credible. Thus, EPA must have a reasonable risk evaluation process that allows it to correct the facts about how a chemical is used.

In that context, it is not useful for EPA to pronounce that the conditions of use for a chemical substance must be “locked down” at the scoping stage. The anticipated process for publicly vetting EPA’s initial list of uses for a particular substance is quite short – just 30 days under the proposed rule.¹⁸ EPA has indicated that its search strategy for identifying potential uses will include Google searches, which have the potential to include sources that are inaccurate or out of date.¹⁹ Thus it is likely that the business community will need to submit information to EPA to correct the record about uses and conditions of use. Some of this information may need to be submitted after the comment period offered in the proposed rule, and possibly even after the deadline for publication of the scoping decision on a chemical substance.

No statute, and certainly not TSCA as revised by the LCSA, requires a federal agency to proceed with regulations based on inaccurate assumptions. An agency can correct its own administrative record. Thus, it is important for EPA to clarify its statement that the conditions of use for a chemical substance must be “locked down” at the time of the scoping decision in the sense of precluding later factual corrections. EPA seems to acknowledge in another part of the preamble that parties can provide “newly discovered information” at later stages of the risk evaluation process.²⁰ We recommend that EPA explicitly recognize that information related to the conditions of use, which comes to light after the scoping decision, can be submitted to, and will be considered by, the

¹⁷ FR Notice, at 7566.

¹⁸ FR Notice, at 7578.

¹⁹ Some industry representatives who have been checking the Use Documents recently circulated by EPA on the “Initial List” of chemical substances slated for risk evaluations, identified under Section 6(b)(2), are reporting information gaps and inaccuracies, particularly among online sources, related to these matters.

²⁰ FR Notice, at 7570.

Agency. Such a clarification is in the best interest of advancing a common goal in this process – assuring that the Section 6 risk evaluations are high-quality products.

3. EPA Should Remove the “Issue Preclusion” Provision at §702.39(c)(6)(iii) from the Regulation

The proposed Risk Evaluation Rule includes a substantive limitation in the public comment provision provided for EPA’s scoping decision. Specifically, §702.39(c)(6)(iii) states, “All comments that could be raised on the matters addressed and issues presented in the published risk evaluation scope document must be presented during this comment period. Any issues not raised at this time will be considered to have been waived, and may not form the basis for an objection or challenge in any subsequent administrative or judicial proceeding.”²¹

This is a remarkable provision. Such a constraint on the public comment process for a TSCA risk assessment has not previously been imposed, or even suggested, by EPA. We also are not aware of another situation in other Agency programs where the right of stakeholders to raise concerns about a risk assessment or a risk management action is cut off at a such a preliminary stage of a complex, multi-year process where subsequent opportunities for public comment are statutorily required.

We do not believe that this “issue preclusion” provision can be justified at all. Certainly it cannot be justified by the weak rationale that EPA offers for this provision in the preamble to the Risk Evaluation Rule. EPA initially discusses this “issue preclusion” provision as part of its strategy for addressing the resource demands associated with its decision that risk evaluations must address every condition of use identified in the scoping phase. EPA states specifically that “It will not be practicable to meet statutory deadlines if stakeholders are free to identify additional conditions of use later in the process – for example, on the proposed risk determination.”²²

As discussed earlier in these comments, EPA’s decision to include every condition of use for a chemical substance in a risk evaluation is a self-imposed obligation that is not required by statute, nor does it make sense as a policy matter. EPA’s unnecessary decision cannot be relied on to provide a compelling rationale for an unprecedented restraint on stakeholder participation. Moreover, it is not at all clear that a public comment about a condition of use submitted during the public comment period on a risk evaluation, would necessarily derail the Agency’s ability to meet statutory deadlines. As provided in Section 6(b)(4)(G), EPA has three years to complete a risk evaluation, with the authority to extend the evaluation an additional six months. Assuming EPA schedules its comment period at a reasonable point within the risk evaluation process, EPA should be able to adapt to additional information about a condition of use submitted as a comment, just as EPA would for any other issue that could be raised during the

²¹ FR Notice, at 7578.

²² FR Notice, at 7566.

comment period. In short, there is no need to impose a punitive limit on stakeholder comments regarding conditions of use, provided early in the risk evaluation process, in order to accomplish the overall objectives of Section 6.

The only other preamble support EPA provides for the “issue preclusion” provision is a representation that this policy reflects a “well-established principle of administrative law and practice”, citing the case Nuclear Energy Institute v. EPA, 373 F.3d 1251, 1290-1291 (D.C. Cir. 2004) (“NEI case”).²³ As noted above, however, this proposed “issue preclusion” provision is actually an unprecedented regulatory provision in EPA practice because the relevant administrative law on this topic is nuanced and highly dependent on the specific procedural facts of individual rulemakings.

In fact, the specific case that EPA has cited provides a useful example of why questions related to fair notice to agencies about stakeholder issues should not be the subject of arbitrary rules like the one that EPA is proposing here. The NEI case involved challenges to a unique, complex rule addressing environmental protections that would apply to the Yucca Mountain site for storage of nuclear wastes. The State of Nevada objected to the adequacy of the federal government’s plan for the site because, according to Nevada, it had not adequately met a statutory requirement that “geologic considerations” should be “the primary criteria” for site selection. EPA has cited the court’s decision on whether Nevada properly raised this issue procedurally during the rulemaking as support for its “issue preclusion” proposal in §702.39(c)(6)(iii).

In its decision, the court concluded that Nevada did not raise this issue during the formal comment period on the regulation offered by the Nuclear Regulatory Commission (“NRC”), but did raise it at a public meeting that occurred about four months after the comment period closed. NRC argued that the comment offered at the public meeting had been submitted too late and that the Commission had made it clear that it was not reopening the comment period in setting up the public meeting. The court, however, looked beyond the NRC representations, noting that the Commission’s comments at the public meeting and the rationale for its final decision suggested that the Nevada comments were considered. The court dismissed the NRC’s procedural objections to consideration of the Nevada comments in the judicial challenge to the rule.

In articulating the principle that guided its decision, the court said, “To preserve a legal or factual argument, we require its proponent to have given the agency a “fair opportunity” to entertain it in the administrative forum before raising it in a judicial forum.”²⁴ Thus, the real message from the EPA-cited case is that the appropriateness of “issue preclusion” in a judicial proceeding depends upon whether stakeholders have given administrative agencies a “fair opportunity” to evaluate an issue or concern raised by stakeholders, looking at the specific facts in individual rulemakings. The case does not actually support the notion that “issue preclusion” should occur if the issue was not raised in a particular comment period specified by the regulatory agency.

²³ Fr Notice, at 7570.

²⁴ NEI case, at 1290.

In the case of this proposed Risk Evaluation Rule, it is particularly inappropriate to create a Draconian bar to issues not raised in the very preliminary stage of the risk evaluation process, a process that is likely to extend over three years or longer, to be followed by a risk management rule process that also would extend over several years. EPA, like any other federal agency should consider comments and information provided by all stakeholders, provided that the Agency has a fair opportunity to evaluate the comments. Such a question is necessarily a case-by-case determination.

Respectfully submitted,

A handwritten signature in black ink that reads "Mark Greenwood". The signature is written in a cursive, slightly slanted style.

Mark Greenwood

On behalf of the Chemical Users Coalition